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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,182	04/09/2004	Robert N. Hamlin	10527-003008	1770
26161 7590 03/06/2007 FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER WOLLSCHLAGER, JEFFREY MICHAEL	
			ART UNIT	PAPER NUMBER
			1732	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/06/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/822,182	Applicant(s) HAMLIN, ROBERT N.	
	Examiner Jeff Wollschlager	Art Unit 1732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-29, 32 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-29, 32 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Applicant's amendment to the claims filed January 12, 2007 has been entered. Claim 26 is currently amended. Claims 30 and 31 have been canceled. Claims 26-29, 32 and 33 are pending. Applicant's amendment to the claims has overcome the 35 U.S.C. 112, first paragraph rejection. Accordingly, the rejection is withdrawn.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 07/411,649, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The '649 application does not provide support for a first layer comprising a first polymeric material including a liquid crystal polymer as recited in independent claim 26. Support for a liquid crystal

polymer as recited in claim 26 is found in U.S. Patent 5,270,086, filed July 9, 1991. Accordingly, the claims in the instant application are afforded a priority date of July 9, 1991.

Terminal Disclaimer

The terminal disclaimer filed on January 12, 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent that issued from U.S. Patent Application 10/839,687 has been reviewed and is NOT accepted. The terminal disclaimer does not comply with 37 CFR 1.321(b) and/or (c) because: The terminal disclaimer was not signed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26-29, 32 and 33 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26-30, 33, and 34 of copending Application No. 10/839,687 in view of Kingsford (U.S. Patent 4,799,717; issued January 24, 1989). The instant claims and the claims found in application 10/839,687 are directed to similar method steps. The differences between the claims are the polymeric materials employed as the first layer in producing a laminated expander member. In instant claim 26, the first layer comprises a liquid crystal polymer. In application 10/839,687, claim 26, the first layer comprises polyetheretherketone or polyetherketone. Liquid crystal polymers, polyetheretherketone and polyetherketone are known to be interchangeable in applications requiring high strength and temperature capabilities while remaining deformable/flexible as evidenced by Kingsford (Abstract; col. 5, lines 23-29). Therefore it would have been obvious to one having ordinary skill to interchange the polymers as is routinely practiced in the art.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26-29, 32 and 33 are rejected under 35 U.S.C. 102(a) as being anticipated by Harvey et al. (WO90/15706; published December 27, 1990).

For applicant's convenience, the citations provided in the rejection are taken from U.S. Patent 5,288,529.

Regarding claim 26, Harvey et al. teach a method of producing a laminated expander member/tube comprising co-extruding a liquid crystal polymer outer layer and an inner layer of a different polymer and forming the parison into the expander member/tube (Abstract; col. 1, lines 24-30; col. 4, lines 48-col. 5, lines 27; col. 7, lines 1-7; col. 10, lines 49-67; col. 11, lines 32-37; col. 11, lines 32-37). The co-extruded layers of the tube are laminated/adhere to each other, meeting the limitation that the second layer is an adhesion layer, as currently presented in the claim and understood by the examiner (Abstract; col. 9, lines 59-67).

As to claim 27, Harvey et al. teach co extruding multiple layers including layers toward an exterior of the expander member relative to the first and second layers (col. 4, lines 66-col. 5, lines 26; col. 10, lines 49-67).

As to claims 28 and 33, Harvey et al. disclose biaxially orienting the first layer and drawing and expanding the parison in a blow mold (col. 2, line 1 – col. 3, line 2; col. 7, lines 1-7)

As to claim 29, Harvey et al. disclose the first layer is liquid crystal polymer (Abstract). With regard to claim 29, the “consisting essentially of” language in the claims is noted. The transitional phrase “consists essentially of” limits the scope of the claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristics” of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). For search and examination purposed, absent a clear indication in the specification of what the basic and novel characteristics actually are, “consists essentially of” will be construed as equivalent to “comprising.” When an applicant contends that additional steps or materials in the prior art are excluded by the recitation “consists essentially of,” applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant’s invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989).

Because no evidence has been set forth on the record to show that the use of a blend of liquid crystal polymers and other polymers would materially affect the basic and novel characteristics of the instantly claimed invention, its use is considered to fall within the scope of the instant claim.

As to claim 32, Harvey et al. employ the same claimed process steps with the same claimed materials under the same claimed conditions. Accordingly, the expander member/tube produced by Harvey et al. necessarily has the same claimed physical properties and effects.

Claims 26-29 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Zdrahala (U.S. Patent 5,248,305; priority date of August 4, 1989).

Regarding claim 26, Zdrahala teaches a method of making an extruded tube/expander/catheter from a multilayer parison comprising coextruding a first layer comprising liquid crystal polymer as the outer layer and a second layer of polymer, internal to the first layer and forming the parison into the tube/expander/catheter (Abstract; col. 2, lines 13-40; col. 4, lines 5-col. 5, lines 35; col. 6, lines 4-26; col. 7, lines 8-32). The examiner notes that Zdrahala does not call the inner layer an adhesion layer. However the examiner further notes that Zdrahala employs materials such as polyurethanes, silicone based polymers and vinyl polymers as the inner layer (col. 4, lines 34-50) and that in the instant specification, polyurethanes, polyvinyl chloride and silicones are provided as examples of materials suitable for the adhesion layer. As such, it follows that Zdrahala employs an adhesion layer as claimed.

As to claim 27, Zdrahala teaches extruding a lubricating coating external to the layers (col. 4, lines 34-61; col. 6, lines 4-26).

As to claim 28, Zdrahala teaches biaxially orienting the layers (col. 1, lines 6-68; col. 2, lines 40-68; col. 4, lines 51-60).

As to claim 29, Zdrahala discloses employment of liquid crystal polymers as the first layer (Abstract). With regard to claim 29, the "consisting essentially of" language in the claims is noted. The transitional phrase "consists essentially of" limits the scope of the claim to the specified materials or steps "and those that do not materially affect the

basic and novel characteristics” of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). For search and examination purposed, absent a clear indication in the specification of what the basic and novel characteristics actually are, “consists essentially of” will be construed as equivalent to “comprising.” When an applicant contends that additional steps or materials in the prior art are excluded by the recitation “consists essentially of,” applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant’s invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989).

Because no evidence has been set forth on the record to show that the use of a blend of liquid crystal polymers and other polymers would materially affect the basic and novel characteristics of the instantly claimed invention, its use is considered to fall within the scope of the instant claim.

As to claim 32, Zdrahala employ the same claimed process steps with the same claimed materials under the same claimed conditions. Accordingly, the expander member/tube/catheter produced by Zdrahala necessarily has the same claimed physical properties and effects.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zdrahala et al. (U.S. Patent 5,248,305), as applied to claims 26-29 and 32 above in view of either of Levy (U.S. Patent 4,490,421) or Montano Jr. (U.S. Patent 5,041,125).

As to claim 33, Zdrahala teaches the method of claim 26 as discussed above, but does not expressly teach drawing the parison and expanding the parison in a blow molding operation. However, Levy (col. 2, lines 24-44; col. 3, lines 63-col. 4, line 5) and Montano Jr. (col. 2, lines 28-47; col. 4, lines 5-24) individually disclose drawing the parison and expanding the parison in a blow molding operation.

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to employ the drawing and blow molding method disclosed by each of Levy and Montano Jr. for the purpose, as disclosed by Montano Jr. (col. 2, lines 24-44) of improving the strength of the tube produced by Zdrahala.

Response to Arguments

Applicant's arguments, see the REMARKS, filed January 12, 2007, with respect to the rejection under Harvey et al. (5,589,236) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made as indicated above.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeff Wollschlager whose telephone number is 571-272-8937. The examiner can normally be reached on Monday - Thursday 7:00 - 4:45, alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on 571-272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JW

Jeff Wollschlager
Examiner
Art Unit 1732


CHRISTINA JOHNSON
SUPERVISORY PATENT EXAMINER

3/2/07

February 27, 2007